

CONFIDENTIAL AND SENSITIVE

November 22, 2019

Donna Kessler, Ph.D.
Research Integrity Officer/Misconduct Review Officer

Re: Confidential Inquiry Report
Duke Reference number 2019-02-WJ
Division of Investigative Oversight/ORI Reference DIO 6843

Dear Dr. Kessler,

Thank you for forwarding the October 21, 2019 Inquiry Report ("Report") from the Standing Committee on Misconduct in Research (SCMR), which is appended to this notice. As you have indicated, while Dr. Jiang was provided with a 30-day review period to comment on the report, she is not able to provide a response until after December 6, 2019. Once her comments are received, I will review and consider them.

I have reviewed the Report and concur with the SCMR's finding that there is insufficient evidence of possible research misconduct to warrant an investigation. I also concur with the SCMR's recommendations for additional corrective actions.

I have determined the following corrective actions will be implemented:

1. The managing editors of the 2012 *Am. Heart J.* (Jiang *et al.*) and 2013 *JAMA* (Jiang *et al.*) publications must be contacted by Dr. Jiang, in collaboration with Departmental leadership, to determine if corrections and/or retractions to the publications are needed.
2. The Department, Dr. Jiang, and appropriate co-authors must review the other REMIT study publications to determine whether the research is accurately represented in those publications and/or if the managing editors of the journals should be contacted about possible corrections or retractions.
3. For a period of 3 years, any grant application, IRB protocol submission, scientific abstract, and/or manuscript developed or authored by Dr. Jiang must be submitted for prior review and approval by an ad hoc reviewer or committee identified by the Dean and Department Chair. The purpose of this process will be to ascertain whether the materials submitted are accurate and meet the current institutional standards for rigor, reproducibility, and quality. The ad hoc reviewer(s) may also make recommendations to the Dean and Department Chair for other actions needed prior to Dr. Jiang proposing, conducting, or reporting research.

4. If Dr. Jiang participates in the conduct of any human subjects' research, she should not consent or enroll subjects, nor determine subject eligibility for study participation, for a period of 3 years. After 3 years, the Dean and Department Chair will confer to determine whether Dr. Jiang may once again participate in these activities as an independent investigator.

5. Prior to proposing or conducting any independent clinical research, Dr. Jiang must obtain certification as a Certified Principal Investigator or Certified Clinical Research Professional from the Association of Clinical Research Professionals (ACRP) or the Society of Clinical Research Associates (SOCRA).

6. Prior to proposing or conducting further research (whether clinical or not), Dr. Jiang must attend and complete the Responsible Conduct of Research Short Course conducted by the Trent Center for Bioethics or an equivalent program.

I thank you and the SCMR members for your efforts in reviewing this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary E. Klotman" followed by a stylized flourish.

Mary E. Klotman, MD
Dean, Duke University School of Medicine
Vice Chancellor for Health Affairs, Duke University

CC: Geeta Swamy, M.D., Associate Vice President for Research & Vice Dean for Scientific Integrity